DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 19, 2014

Zavation, LLC
Mr. Lawrence Walker
Engineering Manager
400 Liberty Park
Flowood, Mississippi 39232

Re: K142271
Trade/Device Name: Zavation Z-Link Lumbar
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVD
Dated: November 25, 2014
Received: November 26, 2014

Dear Mr. Walker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K142271

Device Name
Zavation Z-Link Lumbar

Indications for Use *(Describe)*
The Zavation Z-Link Lumbar is a stand-alone anterior interbody fusion device indicated for use in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S 1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). The interior of the spacer component of the Z-Link Lumbar is to be filled with autogenous bone graft material.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

# 510K Summary

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|---|---|
| Date: | December 19, 2014 |
| Submitter: | Zavation LLC<br>400 Liberty Park Drive<br>Flowood, MS 39232<br>Phone: 601-919-1119<br>Fax: 800-447-1302 |
| Contact person: | Lawrence Walker |
| Type of 510(k) submission: | Traditional |
| Trade name: | Zavation Z-Link Lumbar |
| Common name: | Intervertebral Fusion Device with Integrated Fixation, Lumbar |
| Classification regulation: | 21 CFR 888.3080 Intervertebral body fusion device |
| Device classification: | Class II |
| Classification Panel: | Orthopedic |
| Product code: | OVD |
| Basis for submission: | New device |

**Device Description:**
The Zavation *Z-Link Lumbar* includes a PEEK spacer, titanium interbody plate and screws. The spacer component is assembled to an interbody plate and implanted anteriorly. The endplate contacting surfaces of the spacer component include serrations, and the plate component includes four holes for inserting two bone screws in each vertebral body. The plate component also includes a screw lock at each hole. The bone screws are available in a variety of diameters and lengths. The interbody plate components are available in a variety of heights. The spacer components are available in a variety of depths, widths, and heights.

**Intended Use:**
The Zavation Z-Link Lumbar is a stand-alone anterior interbody fusion device indicated for use in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S 1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). The interior of the spacer component of the Z-Link Lumbar is to be filled with autogenous bone graft material.

**Materials:**
The spacer component is manufactured from medical grade PEEK Zeniva ZA-500 (ASTM F2026) with a Tantalum alloy position marker (ASTM F560). The plate and screws are titanium alloy (ASTM F136).

**Predicate Devices:**
Synthes SynFix-LR (K072253) - Primary
Zavation IBF System (K120576)

**Performance Data:**
Mechanical test results demonstrated that the Zavation Z-Link Lumbar is substantially equivalent to the predicate devices. Testing was performed in accordance with:

- ASTM F2077, Test Methods for Intervertebral Body Fusion Devices
    - Static Axial Compression
    - Dynamic Axial Compression
    - Static Shear
    - Dynamic Shear
- ASTM F2267, Standard Test Method for Measuring Load Induced Subsidence of an Intervertebral Body Fusion Device Under Static Axial Compression
- ASTM Draft F04.25.02.02, Static Pushout Test Method for Intervertebral Body Fusion Devices.

**Summary of Technological Characteristics:**
The Zavation Z-link Lumbar device is substantially equivalent to the cited predicate(s) in design, material, and intended use.

**Conclusions:**
The device description and testing completed demonstrate that the device is substantially equivalent to the cited predicates for the stated intended use.